

REMARKS

Claims 1-114 are pending, with claims 8-9, 17-19, 44-45, 51, 60-61, 67-81, 89-90, 97-98, 101, 106, and 108-112 having previously been withdrawn without prejudice. Of the non-withdrawn claims, independent claims 1, 38, 58, 82, 95, 103, 113, and 114 are amended. Of the withdrawn claims, independent claims 67 and 108 are amended. The non-withdrawn claims have been rejected under 35 U.S.C. § 103(a) on the basis of the same art as applied in the previous Office Action (i.e., Alden, Hagen, and in the case of some claims, Simpson), but using a completely different rationale. While Applicants do not agree with the rejections, each of the non-withdrawn independent claims 1, 38, 58, 82, 95, 103, 113, and 114 have been amended in a similar manner to more clearly define around these references.

Applicants' representative appreciates Examiner's willingness to discuss the case during a telephonic interview on December 6, 2007. During the interview, Applicants' representative and Examiner discussed several distinctions between Alden and the claimed inventions. In this regard, the location of the inlet and outlet ports relative to the chamber was discussed. Although no formal agreement was reached, Examiner indicated that amending the claims to clarify such a distinction would be a good starting point for overcoming Alden. The independent claims have been amended in accordance with the distinction discussed during the interview with Examiner.

In the previous Office Action and in reference to Alden, Examiner identified the entrance (302) to chamber (300) as the "inlet port" and the exit channel (316) of chamber (300) as the "exit port" in order to purportedly arrive at the language recited in the independent claims. Applicants pointed out that the entrance (302) and exit

channel (316) each had check valves (312, 314) respectively associated therewith so as to provide blood aspiration from a source (i.e., a finder of a diabetic patient) and then to transport the blood to a second remote location such that blood could not flow back out of the chamber toward the source. To more clearly define over the reservoir of Alden, Applicants amended the independent claims to recite a bidirectional fluid communication aspect of the exit port of the reservoir.

Applicants' amendments and arguments were persuasive to overcome the specific interpretation of Alden as applied by Examiner in the previous Office Action. In the present Office Action, however, Examiner has suggested a new interpretation of the same references to reject the claims. In this new interpretation, Examiner has identified the capillary channel (304) as the "inlet port" and the first check valve (312) as the "exit port" to purportedly arrive at the language recited in the independent claims. Applicants disagree with such an interpretation.

In the first place, Applicants submit that Examiner is engaging in word games by re-defining the aspects of the Alden reference differently than was done in the prior Office Action merely to create a new basis for a rejection that does not lie. Additionally, the particular portion of Alden relied upon by Examiner for this new interpretation fails to satisfy the enablement requirement under 35 U.S.C. § 12, paragraph 1. To that end, Examiner relies on a single sentence of Alden: "Alternately, a single check valve (at location 312) may be present controlling both flow into the chamber 300 via the blood transport capillary channel 304 and flow out of the chamber 300 into an optional alternate exit channel 318." (Alden, paragraph 25, lines 15-18). It is well known that a check valve is a unidirectional flow control device that allows fluid to flow

through the valve in one direction and prevents fluid from flowing through the valve in the opposite direction. Under Examiner's new interpretation, check valve (312) would have to permit fluid flow in more than one direction, which is contrary to the well-known operation of check valves. Thus, check valve (312) would permit blood to enter the chamber (300) from capillary channel (304) but would not permit the blood to flow back through check valve (312) and into exit (318). Simply put, the reservoir of Alden, in accordance with Examiner's new interpretation, would not operate for its intended purpose as the check valve would have to provide flow in more than one direction. Moreover, Alden fails to identify any other type of valve but a check valve. Accordingly, Applicants submit that the reservoir of Alden as put forth in this new interpretation is not properly enabled as required by 35 U.S.C. § 112 and reliance on such a disclosure is improper.

Nevertheless, to advance prosecution of this case, Applicants have amended each of the non-withdrawn independent claims to define over even the new interpretation put forth in the Office Action. To this end, the non-withdrawn independent claims have been amended to recite that the inlet port and the exit port are in fluid communication with the chamber "at separate locations thereof." Such a distinction between the inlet and exit ports relative to the chamber is important for operation of the reservoir in a closed blood sampling system. As explained in our previous response, tubing between a pressure-measuring device and a patient is filled with saline, which flows from a fluid source to the patient, so that the pressure in the tubing corresponds to the patient's blood pressure. The reservoir is disposed in the tubing that is filled with saline. Accordingly, for proper operation of the closed blood sampling system, saline

flows in through the inlet port, through the chamber of the reservoir, out through the exit port, and to the patient. That is not possible under the "new interpretation" given to Alden.

The reservoir of Alden, according to the interpretation put forth by Examiner in the Office Action, is arranged such that the capillary channel (304) (i.e., the "inlet port") is coupled to the check valve (312) (i.e., the "outlet port"), which is then coupled to the chamber (300) through entrance (302). Thus, the "inlet port" and "outlet port" are not in fluid communication with the chamber (300) at two separate locations, but instead are coupled thereto at a single location. Hence, the chamber would not form part of the pressure path as does the device of the claimed invention. Moreover, Hagen and Simpson fail to cure the deficiencies in Alden. Even assuming for sake of argument that one of these references disclosed locating the inlet and exit ports in fluid communication with the chamber at separate locations, modifying Alden to incorporate such features would result in the device as put forth in Examiner's prior interpretation (i.e., wherein exit channel (316) was the "exit port"). As noted above, Applicants successfully overcame the Examiner's prior interpretation through the bidirectional nature of the exit port. For at least the foregoing reasons, Applicants submit that the non-withdrawn independent claims, and therefore the claims which depend therefrom, are allowable.

Furthermore, because generic claims 1 and 113 are allowable, Applicants respectfully request that the Examiner bring back the withdrawn claims previously restricted out of the case. Some of the withdrawn claims depend from non-withdrawn allowable independent claims and are therefore allowable for reasons provided above.

The remaining withdrawn claims are either independent withdrawn claims or depend therefrom. In particular, independent claims 67 and 108 have been amended similar to the non-withdrawn independent claims so as to recite that the inlet and exit ports are in fluid communication with the chamber at separate locations. Accordingly, upon bringing these independent claims back into the case, they and their dependent claims are submitted to be allowable as well.

CONCLUSION

In view of the foregoing, it is respectfully submitted that the rejections have been overcome and the case is now in condition for allowance. Accordingly, a formal Notice of Allowance is solicited at the earliest possible time.

If, for any reason, the foregoing does not place this case in condition for allowance, or if any questions remain, Examiner is respectfully requested to telephone undersigned attorney in an effort to promptly resolve same.

No fee is believed due for this paper other than that for a two-month extension and the fee for a Request for Continued Examination, which fees are submitted concurrently herewith. If any other fee is due, please take this as authorization to charge same to our Deposit Account 23-3000.

Respectfully submitted,
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